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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants: De Francesco, R. *et al.*

Application Number: 10/085,476

Filing Date: February 27, 2002

Title of the Invention: METHOD FOR REPRODUCING IN VITRO THE RNA-DEPENDENT RNA POLYMERASE AND TERMINAL NUCLEOTIDYL TRANSFERASE ACTIVITIES ENCODED BY HEPATITIS C VIRUS (HCV)

Examiner: Huston, Richard G

Art Unit: 1652

REPLY BRIEF

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MERCK & CO., INC.

By

Sheldon O. Heber

Date January 18, 2007

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Response to Examiner's Answer

The claims under appeal are directed to a method for identifying a Hepatitis C virus (HCV) RNA-dependent RNA polymerase inhibitor using HCV NS5B, where NS5B was expressed in either a eukaryotic or prokaryotic heterologous system (referred to herein as "recombinantly expressed HCV NS5B"). As further discussed in Appellants' Appeal Brief, the rejection is based on an invitation to experiment rationale, and fails to consider prior art uncertainties and secondary considerations regarding motivation and expectation of success in obtaining RNA-dependent RNA polymerase from recombinantly expressed HCV NS5B.

The examiner argues the claims are obviousness based on the desirability to characterize and experiment with HCV produced proteins. The Examiner's Answer asserts, "[t]hus the motivation upon which the rejection is based is the referred to motivation to assay the NS5B protein for RNA-dependent RNA polymerase activity, and nothing more." (Examiner's Answer filed 11/20/2006 at page 8, lines 13-15.) The rejection deems a reasonable expectation of success to exist based on merely attempting the assay. (See, for example, Examiner's Answer filed 11/20/2006 at page 10, lines 15-18.)

The rejection improperly fails to consider express limitations provided in the claims. Independent claim 22 describes using recombinantly expressed HCV NS5B and indicates: (a) "incubating *in vitro* a composition comprising HCV NS5B . . . a test compound, under **conditions suitable to produce NS5B RNA-dependent RNA polymerase** activity in the absence of said compound . . ."; and ". . . (b) **measuring** the ability of said compound **to affect** said NS5B RNA-dependent RNA polymerase activity". (Claim 22 emphasis added.) Claim 12 provides a similar description to claim 12, but refers to NS5B purified to apparent homogeneity.

The uncertainties in the art and secondary considerations concerning whether recombinantly expressed NS5B provides RNA-dependent RNA polymerase activity directly impacts on the expectation of success and motivation in obtaining conditions suitable to produce NS5B in the absence of a test compound. The present application successfully establishes that recombinantly expressed NS5B provides RNA-dependent RNA polymerase activity encoded by HCV. In doing so the present application, not the prior art, provides a reasonable expectation of success that such conditions could be obtained.

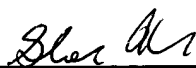
Reference to "measuring" the "affect" indicates that the method provides information on the ability of a test compound to cause a change in RNA-dependent RNA polymerase activity.

The present application illustrates the ability of recombinantly expressed NS5B to provide RNA-dependent RNA polymerase activity. In doing so the present application, not the prior art, provides a motivation to modify a particular set of conditions under which NS5B provides RNA-dependent RNA polymerase activity, by adding a test compound and then measuring the affect of the compound.

The impact of prior art uncertainties and secondary considerations are increased for claims providing additional descriptions such as the use of recombinant protein purified to apparent homogeneity. For example, the skilled artisan would not be motivated to purify recombinantly expressed NS5B to apparent homogeneity and use the purified protein in an assay measuring the effect of a test compound on RNA-dependent RNA polymerase activity, absent a reasonable expectation that the protein could be used to generate RNA-dependent RNA polymerase activity.

Appellants respectfully submit that all the pending claims meet the requirements for patentability. Appellants request that the Board of Patent Appeals and Interferences reverse the outstanding rejections of the claims under appeal.

Respectfully submitted,

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